

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Dupont et al. Confirmation No.: 4677
Serial No.: 10/659,566 Examiner: Timothy E. Betton
Filed: 09/10/2003 Group Art Unit: 1614
Title: PATCH FOR SCREENING THE SENSITIZATION STATE OF A SUBJECT WITH RESPECT TO AN ALLERGEN AND USE THEREOF

CERTIFICATE OF ELECTRONIC TRANSMISSION

I hereby certify that this correspondence is being transmitted electronically to: Examiner Timothy E. Betton, Group Art Unit 1614, United States Patent and Trademark Office, Alexandria, VA 22313-1450, on December 11, 2008.

Lee J. Fleckstein
Agent for Applicants
Reg. No. 36,136

Dated: December 11, 2008

DECLARATION UNDER 37 CFR §1.132

I, Bertrand Dupont, an inventor in the above-identified application, wish to bring the information presented below to the attention of the United States Patent Office.

A – Fischer does not disclose electrostatic forces

1. I have reviewed the content of Fischer (US Patent No 4,836,217). It is my understanding that this reference does not disclose or suggest the use of electrostatic forces. In particular column 5, lines 43-56, Fischer proposes to treat a support either in a Corona discharge chamber or by oxidization to introduce polar structures. These treatments do not create electrostatic forces on a support which would allow the maintaining of a substance in particle form.

2. The techniques of corona discharge treatment or introduction of polar structures into a film have nothing to do with the electrostatic properties of a support. They are methods for increasing the hydrophilicity of a support, e.g., to improve the wettability of a polymeric support by liquids. However, the treatment in a Corona discharge chamber does not create electrostatic forces on the surface of a support.

3. Electrostatic forces designate attraction forces between two opposite charges. Such forces cannot be obtained between a solid (a support) and a gel, because a gel contains water which destroys all electrostatic charges by allowing their circulation and equilibrium in the entire device. The adhesion of a gel on the support, as disclosed in Fischer, therefore cannot imply electrostatic forces. Instead, the gel acts as an adhesive.

4. The use of the Corona treatment in Fischer aims at obtaining a better spreading of the gel on the support. It is a surface treatment, consisting in subjecting the support, for a short period of time, to an electric field which will create, at the surface of the support, polar structures which increase the surface energy and facilitate the spreading of the gel. Such a treatment, however, does not modify in depth the electrostatic properties of the plastic support. To create such electrostatic charges, one would need to subject a support to Corona treatment for long periods of time followed by a heating treatment to allow the charges to penetrate into the thickness of the support to create an electret. No such treatment, however, is disclosed in or contemplated by Fischer.

5. In summary, Fischer does not disclose or suggest any electrostatic forces suitable to maintain a substance, in particle form, on a support.

B - The use of a substance in the form of dry particles is advantageous:

6. I understand from the last office action issued on July 18, 2008, that the Examiner questions the benefits of an electrostatic patch as claimed in the present application. The publication of Kalach et al. (JACI 116 (2005) 1321) shows that, when tested on 49 human subjects, a patch as presently claimed exhibited versus the FINN CHAMBERS, a significantly higher sensitivity (76% vs 44%) and test accuracy (82.9% vs 63.4%). I

would like to mention that these advantageous properties have led to the marketing of such a patch by the company DBV Technology, under trademane Diallesterst.

7. To further illustrate the advantage of the claimed patch over the prior art (e.g., liquid patches), tests were carried out under my supervision to compare the stability of an active substance in the presence or absence of a liquid, in particular, the effect on the stability of powdered milk protein in the presence or absence of water.

8. Protein amounts were determined by the Bradford colorimetric method, using a set of aqueous calibration solutions containing 0 to 16 mg/mL bovine serum albumin (BSA), spectrometric measurements being made at a wavelength of 295 nm.

9. Samples of an aqueous solution comprising 0.5 mg/mL of milk powder were maintained at temperatures of 4°C, 20°C and 37°C, with the following results: after 3 weeks at 4°C and 20°C, the protein content in the samples dropped to 22% and 6%, respectively, of the original amount; after a few days at 37°C, the protein content in the sample had dropped to about 5%.

10. A sample of powdered milk protein having a moisture content of less than 5% was maintained in an air-tight bag at a temperature of 37°C for 3 weeks, after which the protein content was about 22 % of the original amount.

11. A first patch covered with powdered milk containing beta-lactoglobulin, a milk protein, was maintained for 3 months at 25°C and 60% relative humidity under non- airtight conditions, after which the beta-lactoglobulin remaining, as measured by radial immunodiffusion, amounted to less than 0.5% of the total protein content.

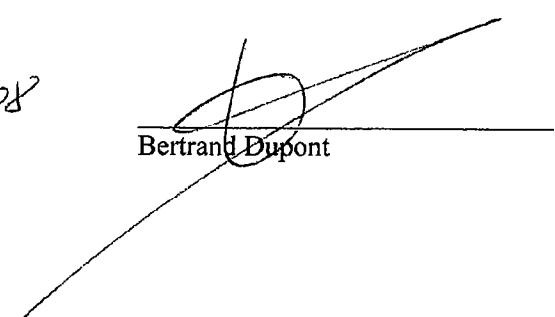
12. A second patch covered with powdered milk containing beta-lactoglobulin was maintained for 2 months at 40°C under dry conditions, after which the quantity of beta-lactoglobulin remaining, as measured by radial immunodiffusion, amounted to about 3.5% of the total protein content.

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13. A comparison of the test results described in paragraphs 11 and 12 provides a clear demonstration of the deleterious effect of adding a liquid or a gel on the stability of an active substance, in particular a protein.

Recognizing that willful false statements are punishable by fine or imprisonment, or both, and further recognizing that such false statements may jeopardize the validity of the application or any patent issuing therefrom, I declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true.

Date November 25th, 2008


Bertrand Dupont